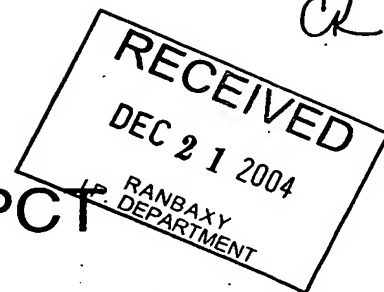


PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY



To:

RANBAXY LABORATORIES LIMITED
c/o DESHMUKH, Jay R.
600 College Road East
Suite 2100
Princeton, NJ 08540
ETATS-UNIS D'AMERIQUE

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing
(day/month/year) 16.12.2004

Applicant's or agent's file reference
RLL-298WO

IMPORTANT NOTIFICATION

International application No.
PCT/B 03/04873

International filing date (day/month/year)
31.10.2003

Priority date (day/month/year)
31.10.2002

Applicant
RANBAXY LABORATORIES LIMITED

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:



European Patent Office
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Tel. +49 89 2399 - 0 Tx: 523656 epmu d
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✓ MRL



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

Applicant's or agent's file reference RLL-298WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/B 03/04873	International filing date (<i>day/month/year</i>) 31.10.2003	Priority date (<i>day/month/year</i>) 31.10.2002
International Patent Classification (IPC) or both national classification and IPC A61K9/00		
Applicant RANBAXY LABORATORIES LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

I ☒ Basis of the opinion

II ☐ Priority

III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability



IV ☐ Lack of unity of invention

V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

VI ☐ Certain documents cited

VII ☐ Certain defects in the international application

VIII ☐ Certain observations on the international application

Date of submission of the demand 20.05.2004	Date of completion of this report 16.12.2004
Name and mailing address of the international preliminary examining authority:  <div style="display: inline-block; vertical-align: middle;"> European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 </div>	Authorized Officer Giménez Miralles, J Telephone No. +49 89 2399-8655 <div style="text-align: right;">  </div>

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/IB 03/04873**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-6 as originally filed

Claims, Numbers

1-21 as originally filed

Drawings, Sheets

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☒ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. : PCT/IB 03/04873

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-21
Inventive step (IS)	Yes: Claims	
	No: Claims	1-21
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB 03/04873

Re Item V

1. The relevant prior art documents are referred to as D1 to D8 as in the order of appearance in the International Search Report (ISR).
2. Citations and explanations supporting the statement with regard to novelty (N), inventive step (IS) and industrial applicability (IA) (Article 33(1) PCT):

- (N) The subject-matter of claims 1-21 is not novel as anticipated by the prior art (Article 33(2) PCT).

D1 discloses an amorphous form of potassium losartan and pharmaceutical compositions containing it. This takes away the novelty of present independent claims 1 and 4.

D2 to D4 disclose crystallization of potassium losartan (form I). First, the potassium salt is synthesized: the free acid form is treated with KOH and concentrated under vacuum prior to crystallization; concentration under vacuum of the reaction mixture must render an amorphous form of the potassium salt; thus an amorphous form is implicitly disclosed in D2 to D4. This takes away the novelty of present independent claims 1 and 4, as well as independent claim 7.

The same reasoning applies in view of D5 to D7, because the step of concentration of a solution or reaction mixture of the potassium salt under vacuum prior to crystallization implies the obtention of an amorphous form as an intermediate form. Thus, the amorphous form is implicitly anticipated. This takes away the novelty of present independent claims 1 and 4, as well as independent claim 7.

The mere spectroscopic characterization of a product or material which has been previously (explicitly or implicitly) disclosed does not establish novelty.

Furthermore, the parametric definition by reference to the figures in claims 2, 3, 5, 6, 20 and 21 is not allowable, because it results in lack of clarity (Art. 6 PCT).

- (IS) The subject-matter of claims 1-21 is not considered to involve an inventive step (Article 33(3) PCT) (see above).

Further, the following consideration is brought to the applicant's attention:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB 03/04873

Selecting spray-drying or freeze-drying instead of vacuum concentration for obtention of the amorphous form would be an obvious alternative for the skilled person (see e.g. D8). No inventive step can be acknowledged for such subject-matter.

- (IA) The subject-matter of claims 1-21 is considered to be industrially applicable (Article 33(4) PCT. The possibility of industrial application is beyond any doubt.